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EXAMINER

FORD, JOHN M

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 09/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/812309

Applicant(s)

Shermovich et al

Examiner

Jim. Ford

Group Art Unit

1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on July 25, 2002
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-12 and 15-24 is/are pending in the application.
- Of the above claim(s) 9-12 and 15-19 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-8 and 20-24 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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Applicants response of July 25, 2002, is noted.

The claims in the application are claims 1--12 and 15--24.

X in claim 1 is now shown as CH or N?

Applicants elected X is CH.

I do not understand. It is well established that a reference for a pyrimidine is not a reference for a pyridine.

How can I allow R4, R5 together?

"R4, R5 together with the sulfur to which they are attached form a three- to eight-membered saturated ring system which is optionally mono or polysubstituted, and which optionally contains 1 to 4 further heteroatoms, where two or more of the substituents optionally form one or more further ring systems;"

Staggering.

This is a compound claim; the right to exclude other <sup>for</sup> 17-20 years from making, using, or selling the compound.

<sup>Let one</sup> cannot even tell what the compound being claim is.

1. 3 to 8 membered ring is a huge undertaking in term of starting materials.

The is a huge undertaking, without the support in the specification for these compounds.

One on reading the claim, does not know what the hetero atoms are or where they are located in this unknown, but claimed ring. Further compounded, in the degree of

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difficultly required to understand the claim, by "optionally one or more further rings"

What do the other rings comprise? Where are these other rings attached? To what?

Alice in Wonderland.

The claim to the unknown rings is made worse by unknown further substituents.

Claim 1 is rejected under 35 U.S.C. 112, 2nd paragraph. What is being claimed?

Claim 1 is rejected under 35 U.S.C. 112, 1st paragraph. Where is the adequate representative exemplification in the spec. for the breadth claimed?

The bald face "heterocyclic", in R6, equally cannot be allowed, for the reasons of record.

What are the unknown substituents?

The art on the 1449 is noted, as an X designation type.

Claim 1 constitutes an improper joinder of inventions as it groups together species inventions that are distinct and separately classified, and will support separate patents. Ex parte Markush, 1925 C.D. 126, provided for this claim structure where there was an emergency engendered need, as the substances were "so closely related that they would not support a series of patents". This is not the case here. Therefore, the instant generic claims constitute an improper joinder of inventions; Ex parte Reid, 105 U.S.P.Q. 251; In re Winnek, 73 U.S.P.Q. 225; In re Ruzicka, 66 U.S.P.Q. 226.

Working on the entire application would be a serious burden, as the examiner is not given the time to search differently classified inventions.

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Claim 1, as written, is an example of an improper Markush Claim, i.e. a reference for one ring system is not a reference for the other. That is the yard stick as to when <sup>FO</sup> require restriction.  
^

Footnote 3 of In re Weber 198 USPQ 330, provides in col. 1 that:

“A Markush-type claim is directed to “independent and distinct inventions,” if two or more of its members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render claim obvious under 35 U.S.C. 103 with respect to the other member(s).”

“If the claim is of the nature, the examiner is authorized to reject it as an improper Markush claim, and for misjoinder, and to require the applicant to restrict the application to a single invention. In making such a requirement, the examiner will (1) clearly delineate the members or groups of members believed to constitute improperly joined inventions, and (2) state reasons fully explaining why they are independent and distinct. Applicant’s response to such a requirement should be an election of a single adequately disclosed and supported invention, with or without restriction of the claim(s) to that invention. Of course, the response must not introduce new matter into the application. See 35 U.S.C. 132 and In re Welstead, 59 CCPA 1105, 463 F.3d 1110, 174 USPQ 449 (1972). A refusal to elect a single invention will be treated as a non-responsive reply.

If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be added without serious burden, the examiner is encouraged to examine it on the merits, even though it is directed to independent and distinct

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inventions. In such a case, the examiner will not follow the procedure outlined in the preceding paragraph and will not require restriction.”

Here, there is extreme burden to expand the search beyond the elected invention, as those variations would control the search in other unsearched area, and the search would have to be rerun with expanded parameters, at additional expense. The examiner is not given the time to search more than one invention, as noted.

Further, in *In re Weber*, 198 USPQ 330 at col. 2.

“Where the examiner has rejected the claim, and required restriction, and the applicant has responded, without restricting the claim(s) to a single invention, the examiner shall, if the position is adhered to, again reject the claim and any other Markush claims not restricted to the elected invention.

No further examination of these claims is required unless and until such rejection has been overcome. However, if the search of the single elected invention develops prior art which would render both the elected invention and the improper Markush claim(s) unpatentable, such prior art may be applied in rejections of both, without a complete search of the subject matter of the improper Markush claim(s). Otherwise, only true generic claims and those restricted to the elected invention will be examined in the usual manner.”

Note MPEP 2173.05 (h):

“Where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does

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not depend on there being a community of properties in the members of the Markush expression.”

Claim 1 need be redrawn to the elected invention, solely, i.e., X is CH.

Claims 2--8 are rejected as being dependent on a rejected claim.

Applicants elected X being CH. Claim 1 need be amended to reflect that election. A reference to a pyridine is not a reference to pyrimidine, Note, footnote 7 of In re Harnisch, 206 USPQ 300, provid for such a restriction.

The practice is set forth in footnote 3 of In re Weber 198 USPQ 330, except the claim here is not rejected under 35 U.S.C. 121, but is restricted to one invention per 37 CFR 1.141, as the examiner is not given the time to examine more than one invention, per application.

Claim 6 is rejected under 35 U.S.C. 112, 2nd paragraph, ~~What~~ what ring is being claimed?

What further hetero atoms are intended? Last line of R8.

Also in claim 8, note heterocyclyl, last word in R10. Heterocyclic chemistry is a huge area of chemistry, before the pyridine elected. The USPTO only recognizes N, O, S, Se and Te as hetero atoms. What do applicants intend? What actual rings are being claimed?

R11 in claim 6 is a run-on-sentence that is not understandable. Note the previous heterocyclyl rejection. R11 is too long to understand.

The placement of the hetero atoms in the unknown rings is not specified. Each arrangement is a different search. The number of combinations possible, even with 1--3 atoms selected for O, N and S, is quite large. R8 is what, in claim 6.

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Adjacent O/S or S/S or O/O combinations are notoriously unstable. See heterocyclic in R6 of claim 1. Note 5 or 6 membered heterocyclyl in the last line of page 113. What is being claimed?

Note "preferably" in claim 7, on p. 114.

R12 is optionally substituted with what? P. 114.

Preferably appear on p. 115, line 4.

R14 and R15 include further unknown substituents, p. 115. Also, R16 is open.

Claims 9--12 and 15--19 stand withdrawn, as not being limited to the elected subject matter.

Claims 20-24 are rejected as being dependent on a rejected claim.

Claim 1 is rejected under 35 U.S.C. 112, 1st and 2nd paragraph, as a result of the use of the words: aryl, heterocyclic and "substituted"....

Judge Smith collected various definitions for aryl, in the footnotes of In re Sus, 134 PQ 301. In view of the fact that aryl means different things to different people, applicants need to indicate in the claims what they intend by aryl. The size of the heterocyclic ring claimed in is R6 unknown. What other hetero atoms may be present?

It appears a sticking point is: "heterocyclic" employed in claim 1. That is staggering. One has no idea what heterocyclic ring forms, or whether 2 hetero atoms, for instance, are next to each other, in R6, or what hetero atoms are present in the unknown size ring.



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The USPTO recognizes a Hetero ring as having C, O, N, S, Se or Te and no other atoms in the ring. Hack Chemical Dictionary recognizes others, that include? P, B and As. Therefore, the term heterocycle is unclear, as it means different things to different people.

The term "substituted", used throughout the claim, produces an indefinite claim, that claims unknowns, as to what the substituents are. See *Corona v. Dovan*, 1928 C.D. 353; 276 U.S. 358.

This is a compound claim. What is being claimed? The heterocyclic term is not set forth in clear, specific language. The reader must produce the heterocyclic ring in question.

Exactly what ring is being claimed must be set forth in the claim.

Conception of what the intended heterocyclic ring, maybe, should not be left to the reader.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification? Note *United Carbon Co. v. Binney Smith Co.* 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable:, at page 386.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic grounds for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide a clear-cut indication of the scope of the subject matter embraced by claim; this ground finds its basis in second paragraph of section 112; second is that language is so broad that it causes to have a potential scope of protection <sup>beyond</sup> that which is justified by

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specification disclosure; this ground stems from first paragraph of section 112, merits of language in claim must be tested in light of these two requirements.

The heterocyclic variable is not believed to meet the requirements of 35 U.S.C. 112, first and second paragraph.

The heterocyclic variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embrace<sup>d</sup> by the claim. The heterocyclic concept is so broad that <sup>it</sup> causes the claim to have a potential scope of protection beyond that which is justified by the specification disclosure. The same is true of aryl.

The heterocyclic ring possible here is wide open to staggering possibilities.

The heterocyclic term is not acceptable, as it reads on the heterocyclic rings that require conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Applicants place too much conception with the reader. The rings include 1, 2,3-thioxazines, Azines, Diazines, Triazines, Tetrazines. Where are the starting materials in the specification? As, P, B in the ring?

One needs to know exactly where in the ring the hetero atoms are: 1,2 or 1,3 ~~or~~ 1,4 or 1,2,4 or 1,3,5, etc., as each is a different entity with a separate search.

These are compound claims, one must clearly know what is being claimed.

One, on reading the indication of heterocyclic applied<sup>d</sup> by applicant, <sup>in R<sub>2</sub></sup> has no idea what size ring is being claimed, or where the hetero atoms are in this unknown ring.

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In regard to heterocycle, broadly, adjacent S or O atoms, in a ring, have not been shown to be producible, as stable, at room temperature. What is the source of the starting material? Where is the adequate representative exemplification in the specification to support the claim language? Someone in the future, may, however, find a way to produce the ring, by reducing the strain, by changing the bond angles.

The heterocyclic term presents a problem of lack of clear claiming, <sup>and</sup> support in the specification for the variables :

This rests specific conception with the reader.

What exactly is intended and where is that supported in the specification? Even any combination of hetero atoms, selected from group consisting of O, S, or N, rests specific conception with the reader. Not a fair burden in return for applicants receiving <sup>a</sup> 17/20 year monopoly.

The possible combinations of any number of hetero atoms, in any combination, in any size ring, is quite large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible, heterocyclic ring <sup>for R<sup>6</sup></sup> is what is needed here. It is not possible to classify and search the molecule unless one knows exactly which heterocyclic ring is being claimed.

The utility here is in regard to anthropolids and helminths. Declarations of unexpected results are often presented in this art. Applicants breadth of heterocyclic produces many different heterocyclic that could easily affect results.

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Applicants need to claim what they have demonstrated as a specific fact.

The heterocyclic expression in claim 1 is not acceptable, as it does not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does not include the source of the starting materials for the rings which might fall within the claim language.

In the chemical compound area, in which applicant now claims, one must be able to tell from a simple reading of the claim what it does and does not encompass.

Why? Because that compound claim precludes others from making, using, or selling that compound for 17/20 years. Therefore, one must know what compound is being claimed.

The written description is considered inadequate here in the specification. Conception should not be the role of the reader. Applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you (the public) find that it works, I claim it, is not a proper basis for patentability. In re Kirk, 153 U.S.P.Q. 48 at page 53.

The claims measure the invention. United Carbon Co. V. Binney & Smith Co. 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of <sup>claim held to</sup> this standard in Lockheed Aircraft Corp. v.s. United States, 193 U.S.P.Q. 449, "Claims measure the invention and resolution of invention must be based on what is claimed".

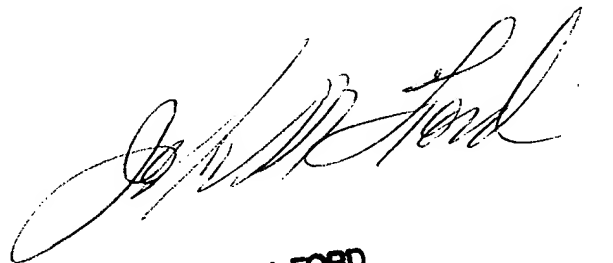
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The CCPA in 1978 held "that invention is the subject matter defined <sup>b</sup>y the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 U.S.P.Q. 11, at 15.

The specification serves various purposes, it sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not <sup>t</sup>to claim, or compounds that stop the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

John M. Ford:jmr

September 9, 2002



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